Patmont Motor Werks
A Nevada Corporation
P.O. Box 1209
Minden, NV 89423
PH 775/782.0113 FAX 775/783.9004 GOPED.COM

K102061

510(K) SUMMARY

SUBMITTER:

Patmont Motor Werks, Inc.
2220 Meridian Blvd.
Minden, NV 89423
Phone: (775) 782-0113 x.215
Fax: (775) 783-9004

Steven J. Patmont

DATE: July 12, 2010

NAME OF DEVICE:

Trade Name: Trevair Chair Adult
Classification Name: Manual Wheelchair - Product Code: IOR

PREDICATE DEVICES:

1) Per4maX Medical, LLC - Shockwave Suspension Wheelchair - K032123
2) Colours - Boing - K945534

INTENDED USE:

The intended use of Trevair Chair Adult is to provide mobility to persons with physical limitations limited to a sitting position. It is intended for indoors and outdoor use by individuals of all ages who are physically challenged. Designed and handcrafted in Minden Nevada, USA, specifically for any individuals who want or need plush suspension at an uncompromising wheel chair weight.

DESCRIPTION OF DEVICE:

Trevair Chair Adult is a self-propelled, rigid frame, mechanical wheelchair consisting of components typical of most manual wheelchairs. It has large rear wheels with push rims for self-propulsion and small front pivoting casters for turning and stability. It is a light weight, user adaptable, everyday chair for use both indoors and outdoors.

SUBSTANTIAL EQUIVALENCE:

The Trevair Chair Adult is substantially equivalent to the listed predicate devices in its specifications, performance and use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Patmont Motor Werks, Inc.
% Mr. Steven J. Patmont
2220 Meridian Boulevard
Minden, Nevada 89423

DEC 13 2010

Re: K102061
Trade/Device Name: Trevair Chair Adult
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: November 17, 2010
Received: November 18, 2010

Dear Mr. Patmont:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(K) NUMBER: Unknown at this time

DEC 13 2010

DEVICE NAME: Trevair Chair Adult

INDICATIONS OF USE:

The intended use of Trevair Chair Adult is to provide mobility to persons with physical limitations limited to a sitting position. It is intended for indoors and outdoor use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102061